The year 2011 has been characterized by uncertainty for those engaged in cancer research and cancer care. Many states and federal agencies began taking steps to implement the Patient Protection and Affordable Care Act of 2010, while the U.S. Supreme Court agreed to hear oral arguments challenging the constitutionality of the legislation. Congress also proposed substantial revisions to Medicare and Medicaid but thus far has been unable to agree on any changes. In addition, the nation’s current fiscal situation focused new attention on the impact of austerity measures on the research budget. At the same time, opportunities for progress in cancer research and care have never been greater, with increased understanding of the molecular underpinnings of cancer and hundreds of novel targeted therapies in development.

This situation presents both new opportunities and new challenges for the advancement of cancer research and care. The Forum and the entire cancer community have the potential to influence future policy decisions as the country debates the fundamental issues in our health care system. The summary of our recent National Cancer Policy Summit outlines key issues identified by leaders in the field as the most pressing policy concerns for cancer that are emerging in this new environment and proposes potential actions to improve care and research.

The activities of the Forum this year focused on several themes important to patients with cancer. For example, the Forum and the National Coalition for Cancer Survivorship brought together stakeholders to discuss ways to improve cancer treatment planning. The Forum also examined the influence of obesity on cancer recurrence and survival, and explored ways to facilitate collaborations for the development of novel combination cancer therapies.

A 2010 Institute of Medicine (IOM) consensus study undertaken with support from the Forum concluded that a national network for conducting large-scale multi-institutional clinical trials is of vital importance, but that many changes are needed to improve the efficiency and effectiveness of the existing Cooperative Group Program. The Forum and the American Society of Clinical Oncology convened a workshop to summarize the progress to date in implementing the recommended changes to our clinical trial infrastructure. Many of the presentations and comments were explicit that the IOM report was driving progress. A new IOM consensus study on the use of “omics”-based tests for predicting patient outcomes in clinical trials, which builds on past Forum work, is also nearing completion.

In looking forward to 2012, planning is well under way for new workshops and follow-on consensus studies on such important topics as informatics needs and challenges in cancer research, reducing tobacco-related cancer incidence and mortality, and improving the quality of cancer care.

John Mendelsohn, M.D.  Patricia Ganz, M.D.
Chair, National Cancer Policy Forum  Vice Chair, National Cancer Policy Forum
About the Forum

The National Cancer Policy Forum (NCPF) provides a continuous focus on cancer policy at the Institute of Medicine. IOM forums are designed to allow government, industry, academic, and other representatives to meet, confer, and plan on subject areas of mutual interest. The objectives of the Forum are to identify emerging high-priority policy issues in the nation’s effort to combat cancer and to examine those issues through convening activities that promote discussion about potential opportunities for action. These activities inform stakeholders about critical policy issues through published reports and often provide input for planning formal IOM consensus committee studies.

NCPF Workshops and Published Reports in 2011

The National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care

Many ongoing changes are likely to have an impact on cancer research and care. For example, technological advances are rapidly changing the way cancer research is conducted, and health care reform legislation has many implications for cancer care. There is a growing emphasis on molecularly targeted therapies, information technology, and patient-centered care, and clinical cancer research has become a global endeavor. At the same time, there are concerns about shrinking research budgets and escalating costs of cancer care.

The NCPF convened key leaders in the cancer community to identify and discuss these changes. The meeting explored policy issues related to cancer research and cancer care, the implementation of health care reform, the delivery of cancer care, and cancer control and public health needs. Expert participants suggested many potential actions to provide patient-centered cancer care, to foster more collaboration, and to achieve other goals to improve research and care. This meeting has been very influential in refining the continuing work of the Forum. A summary of the meeting was published in February 2011 (www.nap.edu/catalog.php?record_id=13101).

Nanotechnology and Oncology

Nanotechnology in medicine—also known as nanomedicine—has the potential to address a number of challenges in cancer care. For example, nanotechnology could improve diagnostic imaging to detect cancer earlier and locate it more accurately, to direct treatments more specifically to cancer cells and avoid causing harm to healthy ones, and to create new tools for cancer prevention. Substantial research funding is currently being devoted to nanomedicine, providing the opportunity for scientific advances and new products. However, there are substantial challenges to using nanomedicine in clinical research and translational science. This workshop explored what nanomedicine is, what it can do, its potential risks and benefits, and how it should be regulated. Discussions focused on the use of nanotechnology in oncology and cancer research, research and development of new cancer nanomedicines, risk management, and public perspectives on nanotechnology. A summary of the workshop was published in February 2011 (www.nap.edu/catalog.php?record_id=13037).

Patient-Centered Cancer Treatment Planning: Improving the Quality of Oncology Care

When people are diagnosed with cancer they face many difficult treatment decisions. The complexity of cancer therapy and the fragmented nature of the cancer care system can impede patients’ access to coordinated care and the development of comprehensive treatment plans. Studies indicate that cancer patients are often dissatisfied with the communication they have with their care providers about treatment and their level of involvement in treatment choice and planning. In addition, patients often lack important information about their diagnosis and care and sometimes have preferences for care that may not align with provider expectations.

The NCPF and the National Coalition for Cancer Survivorship co-hosted a workshop that provided an overview of patient-centered care and cancer treatment planning. Topics discussed included shared decision making, communication in the cancer care setting, patient experiences with cancer treatment, best practices, models of treatment planning and tools to facilitate their use,
Implementing a National Cancer Clinical Trials System for the 21st Century

The National Cancer Institute (NCI) Clinical Trials Cooperative Group Program works to advance patient care and research through studies of new cancer treatments, methods of cancer prevention and early detection, and rehabilitation during and after treatment. Research conducted by the Cooperative Groups has significantly improved cancer prevention and treatment measures, but the program's ability to undertake practice-changing clinical trials is threatened by declining funding, inefficient processes, and extensive government oversight.

The NCPF, together with the American Society of Clinical Oncology, hosted a workshop to examine efforts to implement the recommendations of the IOM consensus report titled *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*. The report concluded that “all participants and stakeholders, including physicians, patients, and health care insurers, as well as NCI, other federal agencies, academia, foundations, and industry, must reevaluate their current roles and responsibilities in cancer clinical trials and work together to develop a more effective and efficient multidisciplinary trials system.”

This workshop convened leaders from all of the cooperative groups, top NCI staff, representatives of industry, and many other stakeholders from around the United States for discussions of how best to achieve the aims underlying the IOM recommendations and to summarize progress thus far. Topics included efforts to consolidate the existing Cooperative Groups, public-private collaboration, funding, and how to ensure broad involvement of patients and health care providers in the clinical trials system. A summary of the workshop was published in September 2011 (www.nap.edu/catalog.php?record_id=13154).

Facilitating Collaborations to Develop Combination Investigational Cancer Therapies

Advances in biomedical research have increased our understanding of the complex nature of disease and the interaction of multiple molecular pathways involved in cancer. Researchers believe that combining investigational products early in their development is a promising strategy for identifying effective therapies. When a combination therapy targets multiple pathways or more than one step in a pathway, it has the potential to confer a greater therapeutic benefit than a therapy directed at a single target. The purpose of this workshop was to identify barriers that may be preventing the development of combination investigational cancer therapies and offer potential solutions for greater collaboration. Topics discussed included scientific challenges and opportunities in the co-development of investigational therapies (both preclinical and clinical); the regulatory environment for co-development, including the recent Food and Drug Administration (FDA) draft guidance on this topic; and organizational, cultural, and legal issues that may be influencing collaboration. A summary of the workshop was published in October 2011 (www.nap.edu/catalog.php?record_id=13262).

The Role of Obesity in Cancer Survival and Recurrence

Obesity rates have been climbing steadily during recent decades, with significant implications for public health. While this trend is discussed most frequently in terms of increased risks for conditions such as cardiovascular disease and diabetes, there are also important implications for cancer. Epidemiological evidence shows that people who are obese or overweight are at increased risk for developing some types of cancer and obesity may affect tumor progression for many cancers.

The mechanisms by which obesity affects cancer survival and recurrence are not fully understood but may include hormonal factors, insulin signaling pathways, adipokines, growth factors, and inflammatory pathways. Many of
these mechanisms could potentially be modified with drugs, as numerous therapies that target these pathways are already used in clinical care or are in development. Because obesity results from an energy imbalance—that is, energy intake is higher than energy expenditure—intravenous energy balance through diet and exercise also have the potential to improve outcomes for patients with cancer. However, much is still unknown about how, when, and where to intervene effectively in obese patients with cancer and how to identify individuals most likely to benefit from obesity-targeted interventions.

Workshop presentations and discussions examined the role of obesity and weight gain in the promotion of various cancers, mechanisms by which obesity may influence cancer progression, strategies for breaking the energy balance–cancer progression link, and potential ways to intervene to improve outcomes for patients with cancer. The published summary will be available in early 2012.

**Follow-on Consensus Study Under Way**

**Review of Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials**
The goal of this study is to examine how tests based on “omics” technologies (e.g., genomics, epigenomics, proteomics, metabolomics) are evaluated and validated prior to use for patient management decisions in clinical trials. The IOM consensus committee completed its draft report, which entered external review in December 2011; the public release of the report is anticipated in early 2012. The report will recommend an evaluation process for determining when omics-based predictive tests are fit for use as a basis for clinical trial design, including stratification of patients and predicting the response to therapy in clinical trials. Information about the committee and its work can be found at: http://iom.edu/Activities/Research/OmicsBasedTests.aspx. This study builds on past IOM consensus reports on biomarker development and evaluation.

**Planning Under Way for Future Events and Studies**

**Informatics Needs and Challenges in Cancer Research**
Informatics are increasingly essential to health research, which includes the full range of data and research activities, from clinical care and health services delivery to bioinformatics and computational biology. Recent devolution of national informatics efforts has left a void in defining appropriate standards, governance, technologies, and privacy protections to ensure a trustworthy public and private resource that catalyzes innovation. There is an urgency nationally to define, understand, and resolve this evolving gap in order to ensure a maximally efficient and effective information system to support research, learning, and health in our future.

The workshop, which will be held February 27-28, 2012, will address topics such as the design and development of informatics in cancer research, standards, interoperability, infrastructure needs, methods for data use, and sustainability. The workshop will also include discussion of potential policy changes to facilitate the effective implementation, adoption, and use of informatics tools in cancer research.

**Reducing Tobacco-Related Cancer Incidence and Mortality**
Tobacco use causes more than 440,000 deaths in the United States—one out of every five deaths—and more than 5 million deaths around the globe each year. Nearly 40 percent of tobacco-related deaths in the United States are due to cancer. The majority of these are due to lung cancer, but there is now sufficient evidence to causally link tobacco use to cancer at 18 different organ sites, including various head and neck, stomach, colorectal, liver, pancreas, cervical, ovarian, bladder, and kidney cancers, as well as myeloid leukemia. Genetic and epigenetic changes lead to cancer through the alteration of critical cellular pathways that foster uncontrolled cell growth and the defeat of normal mechanisms to restrain their growth and spread. An improved understanding of the molecular pathways underlying tobacco carcinogenesis, using new technologies and systems biology approaches, could lead to the development of more effective therapies to prevent and treat tobacco-related cancers. More could also be done to prevent tobacco-related deaths by reducing the use of tobacco.

This workshop, which will be held June 11-12, 2012, will examine ongoing local, state, and federal activities designed to reduce tobacco use, and the new role of the FDA in regulating tobacco products. The workshop will help to identify gaps in the evidence base linking tobacco use and the incidence, progression, and treatment outcomes for various types of cancer, the biological mechanisms responsible for that linkage, and how to target them.
Future Events and Studies (cont.)

Delivering Affordable Cancer Care in the 21st Century
Advances in early detection, prevention, and treatment have resulted in consistently falling cancer death rates in the United States, but the national cost of cancer care is substantial and is expected to increase significantly in the coming decade due to the aging population in the United States. Also, as more expensive targeted therapies and other new technologies become the standard of care, the costs of cancer care are projected to escalate more rapidly in the near future. The goal of the workshop, which will be held October 8-9, 2012, will be to facilitate a dialogue in which all stakeholders in oncology care, including patients and health care professionals, can discuss the root causes of escalating costs in cancer care and suggest potential ways to curb those rising costs while maintaining or improving the quality of care patients receive.

Improving the Quality of Cancer Care: Addressing the Challenges of an Aging Population
Building on previous consensus reports and NCPF workshops, this new IOM consensus study will revisit the quality of cancer care a decade after the IOM report Ensuring Quality Cancer Care was published to see what has changed, what challenges remain, whether new problems have arisen, and how health care reform might affect quality care. The project will emphasize societal challenges arising as a result of the shifting demographics in the United States. For example, the expected workforce shortages resulting from the escalation of cancer cases due to the aging population will affect all age groups. In addition, although the study will consider Medicare payment policy as a model (and major payer for older populations), other payers also face evolving coverage and reimbursement challenges and often follow the lead of Medicare. The study will consider quality of care from the perspectives of key stakeholders, including patients, health care providers, and payers. This project is slated for launch in 2012.

Past Reports from the NCPF

Workshop Reports
From Cancer Patient to Cancer Survivor: Lost in Transition: An American Society of Clinical Oncology and Institute of Medicine Symposium (2006)
Developing Biomarker-Based Tools for Cancer Screening, Diagnosis, and Treatment (2006)
Effect of the HIPAA Privacy Rule on Health Research (2006)
Implementing Cancer Survivorship Care Planning (2007)
Cancer in Elderly People (2007)
Cancer-Related Genetic Counseling and Testing (2007)
Improving the Quality of Cancer Clinical Trials (2008)
Implementing Colorectal Cancer Screening (2008)
Multi-center Phase III Clinical Trials and the NCI Cooperative Group Program (2009)
Ensuring Quality Cancer Care Through the Oncology Workforce (2009)
Assessing and Improving Value in Cancer Care (2009)
Policy Issues in the Development of Personalized Medicine in Oncology (2010)
A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care (2010)
Extending the Spectrum of Precompetitive Collaboration in Oncology Research (2010)
Direct-to-Consumer Genetic Testing (with the National Research Council [NRC], 2010)

Spin-off IOM Consensus Committee Studies
Cancer Biomarkers: The Promises and Challenges of Improving Detection and Treatment (2007)
Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (2009)
Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease (2010)
A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program (2010)
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(as of December 31, 2011)

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Membership of the Forum
(as of December 31, 2011)

Membership of the Forum includes a diverse range of stakeholders from multiple sectors, including government, the pharmaceutical and biotechnology industries, nonprofits, academic health centers, and patient groups.

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Additional Information
For more information about the National Cancer Policy Forum, please visit our website at:
www.iom.edu/NCPF